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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,641	09/25/2003	Thomas E. Wagner	035879-0165	4465
22428 7590 10/26/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
			EXAMINER QIAN, CELINE X	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 10/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/669,641

### Applicant(s)

WAGNER ET AL.

### Examiner

Celine X. Qian Ph.D.

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-60 is/are pending in the application:
- 4a) Of the above claim(s) 1-9 and 21-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20 and 52-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-60 are pending in the application. Claims 1-9, 21-51 are withdrawn from consideration for being directed to non-elected subject matter. Claims 10-20 and newly added claims 52-60 are currently under examination.

This Office Action is in response to the Amendment filed on 8/16/07.

#### ***Response to Amendment***

The rejection of claims 18 and 19 under 35 U.S.C.101 has been withdrawn in light of Applicant's amendment.

The rejection of claims 10-20 under 35 U.S.C.102 (b) or 103 (a) has been withdrawn in view of the new grounds of rejection under 35 U.S.C. 112 1<sup>st</sup> paragraph necessitated by Applicant's amendment.

#### ***New Grounds of Rejection Necessitated by Amendment***

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-20 and newly added claims 52-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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Claim 10 is amended to drawn to a composition comprising a plasmid and at least one nuclear localization signal peptide. The dependent claims 11-17, 52-58 are drawn to the composition of claim 10 and comprising further elements. Claims 18, 20, 59 and 60 are drawn to cells that comprising said composition. Applicants assert that the support for the amendment and the newly introduced claims can be found in original claim 5, 19, 1, 3-7 and 9, paragraph [0039] of the originally filed specification. A review of the entire disclosure of the instant specification does not support Applicant's statement. Claim 10, as originally filed, is drawn to a plasmid comprising at least one construct that comprises, 5'-3', (i) a first arm polynucleotide sequence, (ii) a spacer polynucleotide sequence, and (iii) a second arm polynucleotide sequence, wherein said second arm polynucleotide sequence is the complement of said first arm polynucleotide sequence and wherein said second arm polynucleotide sequence is the opposite orientation of said first arm. According to the disclosure of the instant specification, such plasmid is used for preparation of a nucleic acid drug, wherein said plasmid may be amplified in bacterial cells, and denatured to generate the nucleic acid drug that comprising pairs of hairpin loops, wherein each pair of hairpin is capable of inducing cell apoptosis (see disclosure [0035]-[0040]). In other words, the plasmid is a starting material for the making of the nucleic acid drug. Originally filed claim 5 is drawn to a nucleic acid drug that comprises four pairs of hairpin loops and further comprises at least one nuclear localization signals. It is not drawn to a composition that comprise a plasmid as claimed and a nuclear localization signals. As such, it does not support the current amendment to claim 5. Similarly, claims 1, 3-7, 9 and 19 are drawn to a nucleic acid drug and additional elements, or cells comprising such nucleic acid drugs. It does not support the current amendment to the claims dependent on claim 10 because these claims are now drawn

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to a composition comprising a plasmid and additional elements or cells comprising said composition. The claimed composition including the plasmid and other types of elements is not supported by the specification as originally filed because the specification does not disclose such composition. The specification only provides support for the nucleic acid drug and nuclear localization signal peptide and cells comprising such nucleic acid drug (see for example, [0009]). As such, the amendment to claims 10-18, 20 and newly added claims 52-60 contain material that is not supported by the specification as originally filed. Therefore, it constitutes new matter.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.  
Examiner  
Art Unit 1636

CELINE QIAN, PH.D.  
PRIMARY EXAMINER

